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Original Research Article

## Comparative study on efficacy of myo inositol over metformin in Polycystic ovary syndrome patients

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### ABSTRACT

**Background:** Study aimed to determine the effectiveness of Myo-Inositol over Metformin in women with established diagnosis of PCOS.

**Method:** A total of 90 women diagnosed with PCOS with Vitamin D deficiency included in the study and divided into 3 groups of 30 each. Group A received Tab. Metformin 500mg thrice daily for a period of 24 wks. Group B women received Tab. Myoinositol 2 gm twice daily for a period of 24 wks. Group C women received Tab. Metformin 500mg twice daily with Tab. Myoinositol 2 gm twice daily.

**Results:** After treatment, 26%, 50%, and 80% were showed regular menstrual cycles ( $p=0.001$ ). After 6 months of treatment, there was a reduction of polycystic ovaries in 50% in group A, 80% reduction in group B, and 93.33% reduction in group C respectively. There was a significant reduction in Acne, Hirsutism, BMI, serum LH, FSH, LH/FSH ratio, free testosterone, total testosterone, serum insulin levels, total cholesterol levels were seen at the end of 24 weeks in 3 groups, but higher significance seen in group C.

**Conclusion:** It is thus evident that Myoinositol administration helps to improve insulin sensitivity and can be used in women with PCOS having insulin resistance. Myoinositol helps in reducing metabolic and endocrine abnormalities in PCOS patients. Myoinositol is safe, inexpensive and easily available, its addition to Metformin can contribute for normalization of the dysregulated metabolism in various tissues including ovaries, pancreas, muscle and enhance the action of Metformin in improving the clinical, biochemical features of PCOS.

**Keywords:** Hirsutism, Myoinositol, Metformin, PCOS

### INTRODUCTION

Polycystic ovary syndrome (PCOS) is the most common endocrine disorder of women of reproductive age group affecting approximately, 6-15 % of female population.<sup>1,4</sup> the most widely accepted theory proposes that PCOS is a self-perpetuating cycle of hormonal events with arrested follicular development, increased androgen concentration resulting in polycystic ovaries.<sup>5</sup> PCOS is the most common cause of infertility due to menstrual dysfunction.<sup>6</sup>

PCOS is of multifactorial etiology and attributed to familial, genetic and environmental factors. Familial occurrence is noted among siblings (sisters) and offspring (female children). Environmental factors like stress, lifestyle changes including increased fat and carbohydrate diet and reduced physical activity are important contributing factors.<sup>6,7</sup>

Diagnosis is based on consensus at Rotterdam (2003): Oligo/Anovulation, Hyperandrogenism, polycystic ovaries, with an exclusion of other endocrine disorders.<sup>8</sup>

Anovulation in PCOS is due to inappropriate Gonadotropin secretion. This leads to preferential production of Luteinizing hormone (LH) compared to follicle stimulating hormone (FSH) and LH: FSH ratio becomes 2:1 or even 3:1.<sup>6,9,12</sup> Insulin resistance is common in approximately 60-70% of women with PCOS.

The excess insulin stimulates luteinizing hormone (LH) to produce more androgens from theca cells of ovary leading to features of Hyperandrogenism. Increased androgens prevent maturation of one dominant follicle as Graafian follicle and also prevent apoptosis of small follicles, which are normally destined to disappear.

This gives the appearance of polycystic ovaries in ultrasound as a necklace like pattern in the peripheral rim of ovary.<sup>12</sup>

Metabolic complications include type 2 diabetes mellitus, obesity, dyslipidemia, atherosclerosis, coronary artery disease together called as metabolic syndrome X.<sup>13</sup> Thus, PCOS is not a disease of short-term effects but a syndrome of long-term consequences.<sup>14</sup>

Married women with infertility need ovulation induction.<sup>15</sup> Also, life Style modifications like regular exercise and balanced dietary forms the first line Management.

Recently, Myoinositol (MI) - a novel insulin sensitizer has been developed for treating PCOS with infertility. MI plays an important role as the structural basis for some secondary messengers including synthesis of phosphatidyl inositol 3-kinase (PI 3-kinase), a key messenger to increase glucose uptake, improve insulin sensitivity and thereby reducing insulin resistance. Supplying extra MI appears to temporarily correct the impaired insulin pathways and reduce the signs and symptoms of insulin resistance.<sup>16</sup>

Certain studies have demonstrated that treatment with MI is effective in reducing hormonal, metabolic and oxidative abnormalities in PCOS patients by improving insulin resistance.<sup>17</sup>

Metformin and Myo-inositol being insulin sensitizers correct biochemical parameters, i.e., insulin resistance parameters, hormonal parameters and lipid profile, leading an improvement in menstrual irregularities, hyperandrogenism, and infertility in PCOS in women.

The need for doing this study of demonstrating the efficacy of myoinositol was because of its limited studies available in India till now regarding supplementation of Inositol in PCOS treatment. Aim of the study is to determine the effectiveness of Myo-Inositol over Metformin in women with an established diagnosis of PCOD.

## METHODS

This is a prospective study done in the Department of Obstetrics and Gynaecology, Narayana medical college and Hospital, Nellore for 2 years (NOV 2016-NOV 2018). This study was designed to compare the efficacy of Myoinositol over Metformin in PCOD patients.

Women attending to Gynaecological Department, Narayana Medical College and Hospital, Nellore with complaints of menstrual irregularities/hirsutism/acne are recruited.

### *Inclusion criteria*

Women diagnosed PCOS between ages 15-35 yrs are included in the study.

### *Exclusion criteria*

Subjects who have conceived in a period of study; subjects with lost to follow up; subjects taking infertility treatment; subjects who underwent any surgical procedures during the study; subjects with cardiac/renal/hepatic/thyroid disorders and hyperprolactinemia; subjects with Cushings/pituitary/diabetes mellitus/congenital adrenal hyperplasia/ovarian/adrena neoplasm; subjects on medications (ex; ocp, insulin sensitivity drugs, statins, radioactive iodine, Levothyroxine, Corticosteroids, GnRH agonists and antagonists).

### *Patient analysis*

The institutional ethical committee of Narayana medical college and hospital, Nellore, Andhra Pradesh has approved the study with the following considerations:

No bias with respect to age and pre-treatment BMI, A written informed consent to be taken from all subjects after explaining them, regarding the study and then they were included in the study, Confidentiality should be maintained.

The present study was a prospective, open-labeled, parallel arm, randomized control study to evaluate the efficacy and safety of Metformin versus MI in women with PCOS during the study period of 24 weeks. Total of 100 patients was screened according to Rotterdam criteria, out of which 90 PCOS patients who fulfilled the inclusion and exclusion criteria were recruited for this study after obtaining informed consent from the patients.

The selected study subjects were randomly divided into three groups of 30 each. Subjects in each group were treated as follows and continued without any change in the treatment for the entire duration of the study.

**Treatment plan**

Group A: (n = 30) Tab. Metformin 500mg thrice daily (standard drug).  
 Group B: (n = 30) Tab. Myo inositol 2gm twice daily (study drug).  
 Group C: (n = 30) standard drug+study drug. Tab. Metformin 500mg twice daily with Tab. Myo inositol 2gm twice daily.

The cases were followed and response to treatment was assessed (menstrual cycles, hyper androgenic features, insulin resistance, ovarian morphology and volume) after six months.

Variables considered were Weight, BMI, Acne, Hirsutism, serum total testosterone, serum free testosterone, serum fasting insulin, FBS, LH, FSH, LH/FSH ratio, Total cholesterol, TGL, Ovarian Morphology.

Parameters such as height, weight and BMI were recorded. The degree of hirsutism was assessed using the modified Ferriman and Gallway scoring system. This system grades terminal hair growth on a scale from 0 (no terminal hairs) to 4(extensive terminal hair growth) on 9 anatomical sites (upper lip ,chin, chest, upper back, lower back, upper abdomen, lower abdomen, arm, and thigh.) and sum of nine areas generate an overall hirsutism score. Total score <6–normal, 6-8 mild, 8-15 moderate, >15 overt hirsutism. Menstrual cycles, acne are noted from the patient history and clinical examination. Ovarian parameters are obtained by Transabdominal ultrasound using Philips HD 11 machine.

**Statistical analysis**

Statistical analysis has been done by using IBM SPSS Version 20.0. To test the association between the groups, chi-square test was used. For continuous variables, the values are represented as mean and standard deviation. To test the mean difference between two groups, student’s t-test (Independent sample t-test/paired sample t-test) was used. To test the correlation between the groups, Pearson’s correlation was used. All p values are having less than 0.05 are considered as statistical significant.

**RESULTS**

The Mean age was similar in all the three groups. There was no statistically significant difference between the groups. 25.47±5.96, 25.9±6.00, and 25.9±6.09 respectively. The mean BMI after treatment in all the three groups is 25.54, 25.24, and 24.52 respectively. Reduction in mean BMI was more in group c compared to group A, and group B and is statistically significant (Table 1). Acne before treatment was noted in 70% of women in group A, and 66% in group B, 70% in group c, which is almost similar. After treatment, Acne in group A is reduced by 50% after treatment, in group B it is absent in 73%, and in group C acne is absent in 86% of cases. There was significant improvement post-treatment in group C compared to other groups and is statistically significant.

The Mean score of Hirusitism in group A, group b, group C before treatment was 13.43, 12.13, 14.50 respectively. And the p value is 0.226.

**Table 1: Hirusitism after treatment between groups.**

Hirusitism score	Group A		Group B		Group C		P value
	(n=30)	%	(n=30)	%	(n=30)	%	
7-12	8	26.6	10	33.33	12	40.0	<0.0001
13-15	4	13.33	4	13.33	3	10.0	
>15	2	6.66	0	0	0	0	
Mean	10.50		8.73		11.73		

**Hirusitism before and after between groups**

At the end of the treatment women with severe hirsutism was zero in group B and group C. The mean score in group A was 10.43, in group B was 8.73, and in the group, C was 11.73 and was statistically significant.

**Menstrual abnormalities before treatment**

The majority of women in group A were with oligomenorrhea (40%) and irregular cycles (40%), in group B 40% were with oligomenorrhea and 36% were

with irregular cycles, in group C 36% were with oligomenorrhea and 40% with irregular cycles, which is similar in all groups.

At the end of the treatment, 26.6% of women in group A were with regular cycles, 50% of women in group B were with regular cycles, 80% of women in group C were with regular cycles. Thus there was a significant improvement in regularization of menstrual cycles in group C, receiving metformin and myoinositol when compared to group A and group B.

Polycystic ovaries were present in all the three groups, which is similar in all the three groups.

**Ovarian morphology (polycystic ovaries) after treatment**

After treatment, polycystic ovaries were reduced by 50% in group A, 80% in group B, 93.33% in group C. There was a significant reduction in group C treated with metformin plus myoinositol, and is statistically significant. The mean of free testosterone in Group A, B, C were 10.78, 10.91, 11.38 respectively, which were similar before treatment in all the three groups.

After treatment, mean free testosterone after treatment in group A is 10.21, in group B is 10.50, and in the group, C is 6.59. There was a significant reduction in mean free testosterone in group C compared to other groups and is statistically significant.

Reduction of free testosterone at the end of treatment was statistically significant and was maximum in group C. On reducing the free testosterone, significant improvement is observed in Group C at the earlier stage and also at the end of the treatment. It is found that Group C achieved higher control of free testosterone than group A and B. The mean in the reduction of free testosterone for group C after treatment showed statistical significance with a p-value of 0.002.

**Total testosterone (ng/dl) before and after treatment**

Mean of total testosterone before treatment in group A is 0.89, in group B is 0.97, and in the group, C is 1.09 .mean total testosterone after treatment in group A is 0.78, in group B is 0.85, and in the group, C is 1.06.

**Table 2: Mean of serum fasting insulin (mg) before and after treatment.**

Groups	Before treatment		After treatment	
	n	Mean fasting insulin (mg)	n	Mean fasting insulin (mg)
Group A	30	10.55	30	9.75
Group B	30	10.04	30	10.22
Group C	30	10.31	30	7.75
P-value	0.891		0.007	

It is found that Group C achieved good glycemic control of fasting insulin than Group A and B. The mean of fasting insulin for Group C after treatment was statistically significant with p<0.05 on comparing with other Groups (Table 2).

**Mean of LH (miu/ml) before and after treatment**

Mean LH Levels in all the three groups at baseline and at the end of treatment group C had significant reduction of LH after treatment when compared with group A and B. The mean of LH after treatment was significantly reduced in Group C which is 7.23, compared to group A and B which were 10.78 and 10.96 respectively. It is found that Group C achieved more statistical significant (p<0.0001)

at the end of treatment with high control of LH than the other groups.

**Table 3: Mean of FSH (miu/ml) before and after treatment.**

Groups	Before treatment		After treatment	
	n	Mean	n	Mean
Group A	30	4.94	30	5.84
Group B	30	5.30	30	5.70
Group C	30	4.89	30	4.66
P-value	0.127		0.019	

The mean levels in the reduction of FSH after treatment for Group C were statistically significant than Group A and B (Table 3).

**Table 4: Mean of LH/FSH ratio before and after treatment.**

Groups	Before treatment		After treatment	
	n	Mean	n	Mean
Group A	30	2.42	30	2.06
Group B	30	2.37	30	2.12
Group C	30	2.50	30	1.59
P value	0.506		0.001	

The mean LH/FSH level was lowered by group C, and group A and this reduction of LH/FSH level by both drugs after treatment showed statistical significance. Maximum reduction of LH/FSH level after treatment was observed in group C. Group C achieved significant control of LH/FSH than group A and B (Table 4).

**Table 5: Total cholesterol levels before treatment between groups.**

T. cholesterol	Group A		Group B		Group C	
	n	%	n	%	n	%
<160	0	0	0	0	0	0
160-180	8	26.66	7	23.33	8	26.66
181-200	10	33.33	10	33.33	10	33.33
201-220	12	40.0	13	43.33	12	40.0

There was a significant reduction in cholesterol levels in group C compared to group A and B.

**Mean of T.cholesterol levels before and after treatment**

Mean of T. cholesterol before treatment in group A, B, C were 197.21, 196.60, 191.60 respectively. Mean T. cholesterol levels in group A and B after treatment are 186.51, 178.47 respectively, whereas in group c it is 158.33 showing significant reduction compared to other groups and is statistically significant (Table 5).

The mean TGL levels after treatment in group A and group C were 105.13 and 98.97 respectively which were

reduced compared to group B. Group C significantly reduces triglyceride levels after treatment. It is observed that group C achieved a reduction in triglyceride levels than group A and B, but it is not statistically significant.

**Table 6: Mean of TGL levels before and after treatment between groups.**

Groups	Before treatment		After treatment	
	n	Mean	n	Mean
Group A	30	106.43	30	105.13
Group B	30	100.08	30	106.14
Group C	30	107.73	30	98.97
p value	0.259		0.375	

## DISCUSSION

Insulin-sensitizing agents have been recently suggested as the therapy of choice for polycystic ovary syndrome (PCOS) since insulin resistance, and associated hyperinsulinemia is recognized as critical pathogenetic factors of the syndrome.

The results showed a combination of Myo-Inositol to Metformin seems to have significant results. Though Metformin therapy also had a considerable effect, the combination seems to be more potent. Our study is limited by smaller sample size, shorter duration, and limited resources. More widespread randomized and controlled empirical attempts seem necessary to determine the possible useful aspects of Myo-Inositol on different features of PCOS.

Our study had a decrease in BMI from a mean of 24.02 to 23.07. Our study also showed decrease in BMI treated with myo-inositol group, from a mean of 24.61 to 23.55. In group C showed significant reduction in post-treatment BMI, in correlation with Genazzani et al. and Minozzi et al.<sup>10,18</sup>

The present study showed a 56.6% improvement in positive acne cases after six months of treatment. On comparing the efficacy of three groups, group A showed 46 %, group B 40% and group C showed 56.66% reduction in positive acne cases. This shows significant differences between the two groups regarding acne reduction.

Our study showed regularization of menstrual cycles in 26% of people. In the studies of Susanne Tan et al. showed an improvement in menstrual cycles after treatment with Metformin for six months with 50% and 57.5% respectively.<sup>20</sup>

The present study, showed an improvement in regularization of cycles by 46% after six months of treatment which is on par with other studies. In our study, in group C treated with both metformin and myo-inositol

percentage of reduction of menstrual cycles is 76%.

In studies done by Nestler et al. showed post-treatment serum total testosterone as 0.35.<sup>21</sup> In our study mean of post-treatment serum testosterone is 0.78, well correlated with Martino M zacchi et al. In studies done by Nestler et al. Martino M zacchi et al. showed post-treatment serum total testosterone as 0.65, 0.72, respectively.<sup>21,22</sup>

In our study mean of post-treatment serum testosterone is 0.85, well correlated with Martino M zacchi et al.<sup>22</sup>

Nestler et al. in their study in showed a decrease in mean serum fasting insulin by 40% after 6months of treatment with Metformin.<sup>21</sup> The present study showed, after six months of treatment a reduction in fasting serum insulin value from 10.55 to 9.75.

Nestler et al. Genazzani et al. showed mean serum fasting insulin post-treatment as, 6.3, 8.2 respectively.<sup>21,23</sup> Nestler et al. Genazzani et al. showed mean post-treatment serumfasting insulin levels as 7.3, 9.2 respectively.<sup>21,23</sup>

In our present study treated with both myo-inositol and metformin, mean serum fasting insulin post-treatment is 7.75, well correlated with Nestler et al.<sup>21</sup> In our study, done in group A treated with Myo-inositol plus metformin, post-treatment mean LH/FSH ratio is 1.59, which is in correlation with Angik et al.<sup>24</sup>

In the studies done by M. Minozzi et al. Nehra et al. showed post- treatment mean total cholesterol levels as 170.26, 171,164 respectively.<sup>18,21</sup> In our study done in group A treated with Metformin, post-treatment means total cholesterol level is 186. In the studies done by M. Minozzi et al. showed post- treatment mean Triglyceride levels as, 95.<sup>18</sup> In our study done in group A treated with Metformin, post-treatment means Triglyceride level is 105.13.

In studies done by M.Minozzi et al. mean Triglyceride levels post-treatment were 143.<sup>18</sup> In our study done in group B treated with Myo-inositol, post-treatment mean Triglyceride level is 106.14. In our study, done in group C, mean Triglyceride post-treatment showed 98, withstatistically significant value.

The limitations of this study are study required more number of samples, and multicentre mode study to acquire generalized implications.

## CONCLUSION

PCOS is the most common endocrine problem affecting the women from menarche to premenopausal age. As PCOS is an emerging disorder during adolescence, early intervention is necessary to improve the reproductive health of adolescents and to prevent future complications. A variety of treatment strategies have been developed based on the patient symptomology and need. Insulin

sensitizers especially Metformin has proven efficacy in the treatment of PCOS for a long time. Myoinositol supplementation in addition to Metformin has shown potential therapeutic benefits in improving the hormonal milieu and a variety of PCOS related symptoms mainly menstrual regularity, ovulation and some features of hyperandrogenism. It is concluded from the present study that MI (non-hormonal drug) was effective in the treatment of PCOS. It was a safe and effective drug regarding very minimal or absence of side effects compared to Metformin. The observations made from this study justify the use of MI for the treatment of PCOD. Further research with the ideas of finding out the exact mechanisms including a genetic expression for multiple illnesses of the PCOS is required.

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